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APPLICATION NO. FILING DA		LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/914,720 12/26/2001		Olivier Favre	MPM/ph/13504-USA	2560		
466	7590	01/28/2004	EXAMINER			
YOUNG &		:	BIANCO, PATRICIA			
745 SOUTH ARLINGTO		REET 2ND FLOOR 2202		ART UNIT PAPER NUMBER		
	•			3762	В	

Please find below and/or attached an Office communication concerning this application or proceeding.

			<b>182</b> .					
		Application	n No.	Applicant(s)				
		09/914,720		FAVRE, OLIVIER				
	Office Action Summary	Examiner		Art Unit				
		Patricia M 8	Bianco	3762				
Period fo	The MAILING DATE of this communication or Reply	appears on the	cover sheet with the c	correspondence addres	is			
THE - Exte after - If the - If NO - Failt - Any	ORTENED STATUTORY PERIOD FOR REMAILING DATE OF THIS COMMUNICATION IN COMMU	DN. R 1.136(a). In no ever n. a reply within the statut priod will apply and will tatute, cause the applic	ory minimum of thirty (30) day expire SIX (6) MONTHS from cation to become ABANDONE	nely filed s will be considered timely. the mailing date of this commu D (35 U.S.C. § 133).	nication.			
1)⊠	Responsive to communication(s) filed on 2	<u> 26 December 20</u>	<u>01</u> .					
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ 7	This action is no	n-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposit	ion of Claims							
4)⊠	Claim(s) 1-10 is/are pending in the applica	tion.						
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)□	Claim(s) is/are allowed.							
6)⊠	☑ Claim(s) <u>1 and 3-10</u> is/are rejected.							
7) 🛛	☑ Claim(s) <u>2</u> is/are objected to.							
8)[	Claim(s) are subject to restriction ar	nd/or election re	quirement.					
Applicat	ion Papers							
9)🖂	The specification is objected to by the Exar	niner.						
10)⊠	The drawing(s) filed on 26 December 2001	is/are: a)⊠ ac	cepted or b)□ object	ted to by the Examine	۲.			
	Applicant may not request that any objection to	the drawing(s) be	e held in abeyance. Se	e 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including the co							
11)⊠	The oath or declaration is objected to by the	e Examiner. Not	te the attached Office	Action or form PTO-1	·52.			
Priority	under 35 U.S.C. §§ 119 and 120							
* 5 13)	Acknowledgment is made of a claim for for All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the application from the International Buse the attached detailed Office action for a Acknowledgment is made of a claim for domince a specific reference was included in the 7 CFR 1.78.  Acknowledgment is made of a claim for domince a claim for domince a claim for domince acknowledgment is made of a claim for domesterence was included in the first sentence of the foreign language.	nents have been priority docume ireau (PCT Rule ilist of the certification priority under first sentence provisional appressic priority undestic priority undestication undest	n received. In received in Application the have been received in 17.2(a)). It is decopied not received der 35 U.S.C. § 119(of the specification of the specification has been received der 35 U.S.C. §§ 120	ion No ed in this National Star ed. e) (to a provisional appring an Application Dat ceived. and/or 121 since a sp	plication) a Sheet. pecific			
Attachmer								
2) Notice	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948 mation Disclosure Statement(s) (PTO-1449) Paper No			(PTO-413) Paper No(s) Patent Application (PTO-152 ion.				

U.S. Patent and Trademark Office PTOL-326 (Rev. 11-03)

#### **DETAILED ACTION**

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## **Priority**

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/IB00/00216, filed on February 28<sup>th</sup>, 2000.

#### Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It was not executed in accordance with either 37 CFR 1.66 or 1.68.

## Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant's abstract contains the legal phrase comprises, which should be avoided.

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Art Unit: 3762

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The use of headings throughout the specification to indicate the order or sections of the specification is suggested.

## Claim Objections

Claim 1 is objected to because of the following informalities: claim 1 recites "an evacuation product (28) and an "evacuation conduit (28)" in lines 10 & 16 respectively. It appears to the examiner that applicant is intending for reference no. (28) to be an evacuating conduit for removing product from the purification means. However, clarification is requested. For purposes of examination they have been considered to both be an evacuation conduit.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (i) Claim 1 recites the limitation "provided with a segment adapted to serve as a pump body" in lines 11-12. It is unclear as to what applicant is claiming. Is it tubing connected to a pump or a pump? How does a segment serve as a pump body?
- (ii) Claim 1 recites "a connection conduit (8) extends between the downstream end of said segment adapted to serve as a pump body and said bubble trap (7)" in lines 19-21." It is unclear what applicant is claiming. Is it tubing connected to the bubble trap and pump or a bubble trap and pump? How does a segment serve as a pump body and a bubble trap?

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson, IV et al. (4,888,004). Williamson disclose a tubing network for use as part of a blood processing system having a tubing loop and blood collection (12) and return (14) needles. The needles are enclosed within enclosure (16), thereby providing an open circuit or loop. The tubing network also comprising a blood withdrawal or extraction tubing portion (26) and a blood return (54) tubing portion, both tubing portions are in communication with pumps (27 & 70 respectively). The filter device (32), which separates whole blood into components, is connected to the tubing portions and is seen to be equivalent to applicant's "purification means" since no distinguishing structure was defined by applicant. The network also includes a saline/substitution fluid supply (66) by means of tubing portions (62, 68). Williamson also disclose an air/bubble trap (50) as part of the tubing network or loop. The network further has a tubing line (38) to deliver filtrate from the filter device (32) into collection bags (46a, 46b). Line (38) is seen to be equivalent to applicant's "evacuation conduit 28" since they perform the same function, that of removing (i.e. rejecting product into a chamber by the purification means), and bags (46a, 46b) is seen to be equivalent to applicant's "recovery chamber 15" since they perform the same function, that of holding the filtrate/product rejected

since no distinguishing structure was defined by applicant. With respect to the limitation "provided with a segment adapted to serve as a pump body" in lines 11-12, for purposes of examination, as best could be understood the limitation has been treated as a segment of tubing connected to a pump. With respect to the limitation " a connection conduit (8) extends between the downstream end of said segment adapted to serve as a pump body and said bubble trap (7)" in lines 19-21, for purposes of examination, as best could be understood the limitation has been treated as segments of tubing connected to the bubble trap and to a pump. Williamson discloses tubing connected to the pumps and to the bubble trap throughout the tubing network. With respect to claim 5, Williamson discloses the use of a clamp (64) in line (62) to control fluid flow from the saline supply into the blood return lines, which is seen to be equivalent in structure and function to the "switching means" since no distinguishing structure was defined by applicant. With respect to the limitations of claims 7-10, they are functional recitations of using the device. The functional recitations have not been given patentable weight because t is in narrative form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC § 112, 6<sup>th</sup> paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. In re Fuller

#### Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base

claim and any intervening claims. The subject matter that could either not be found or was not suggested in the prior art of record was the buffer reservoir in the circulation loop in a downstream location of the purification means in combination with the other elements (or steps) in the claims.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Morris (WO 98/22165) discloses a tubing cassette for use in blood treatment methods and systems comprising a plurality of tubing, pumps and integrated components required in blood treatment sessions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.

January 24th, 2004

Patricia M Bianco Primary Examiner Art Unit 3762